

§ 522.2640

drug to use by or on the order of a licensed veterinarian.

[70 FR 39918, July 12, 2005, as amended at 71 FR 57416, Sept. 29, 2006; 72 FR 54540, Sept. 26, 2007; 73 FR 6018, Feb. 1, 2008; 73 FR 58872, Oct. 8, 2008; 74 FR 53165, Oct. 16, 2009]

§ 522.2640 Tylosin.

(a) *Specifications.* Each milliliter of sterile solution of 50 percent propylene glycol with 4 percent benzyl alcohol contains 50 to 200 milligrams of tylosin activity (as tylosin base). Tylosin conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled "Determination of Factor Content in Tylosin by High Performance Liquid Chromatography," which is incorporated by reference. Copies are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) *Sponsors.* (1) See No. 000986 in § 510.600(c) of this chapter for use in paragraphs (e)(1), (2), and (3) of this section.

(2) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1) and (2) of this section.

(c) [Reserved]

(d) *Related tolerances.* See § 556.740 of this chapter.

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* 8 milligrams per pound of body weight once daily.

(ii) *Indications for use.* Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Arcanobacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Arcanobacterium pyogenes*.

(iii) *Limitations.* Administer intramuscularly for not more than 5

21 CFR Ch. I (4-1-10 Edition)

consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 10 milliliters per site. Do not use in lactating dairy cattle. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not administer within 21 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount.* 4 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of swine arthritis caused by *Mycoplasma hyosynoviae*; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

(iii) *Limitations.* Administer intramuscularly for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 5 milliliters per site. Do not administer within 14 days of slaughter. If tylosin medicated drinking water is used as followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

(3) *Dogs and cats*—(i) *Amount.* 3 to 5 milligrams per pound of body weight at 12- to 24-hour intervals.

(ii) *Indications for use*—(a) *Dogs.* Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by *Staphylococci* spp., hemolytic *Streptococci* spp., and *Pasteurella multocida*.

(b) *Cats.* Treatment of upper respiratory infections when caused by *Staphylococci* spp. and hemolytic *Streptococci* spp. and for feline pneumonitis when caused by tylosin susceptible organisms.

(iii) *Limitations.* For intramuscular use only. If there is no response to therapy in 5 days, diagnosis and treatment should be reassessed. Use a 50-milligram-per-milliliter solution only. Dogs and cats receiving a dose of less than 50 milligrams (1 milliliter) should

be dosed with a tuberculin syringe. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 48643, Oct. 2, 1981, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 49841, Dec. 5, 1985; 50 FR 50292, Dec. 10, 1985; 53 FR 40728, Oct. 18, 1988; 59 FR 14365, Mar. 28, 1994; 62 FR 35077, June 30, 1997; 68 FR 24879, May 9, 2003; 70 FR 16935, Apr. 4, 2005. Redesignated and amended at 74 FR 11644, Mar. 19, 2009]

§ 522.2662 Xylazine.

(a) *Specifications.* Each milliliter (mL) of solution contains xylazine hydrochloride equivalent to:

- (1) 20 milligrams (mg) xylazine.
- (2) 100 mg xylazine.
- (3) 300 mg xylazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(3) Nos. 000859 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1); and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(4) No. 061690 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section; and product described in paragraph (a)(3) of this section as in paragraphs (d)(3)(i), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 0.5 mg/pound (lb) intravenously or 1.0 mg/lb subcutaneously.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a

preanesthetic to local or general anesthesia.

(2) *Horses*—(i) *Amount.* 0.5 mg/lb intravenously or 1.0 mg/lb intramuscularly.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(iii) *Limitations.* Not for use in horses intended for food.

(3) *Elk and deer*—(i) *Amount.* Administer intramuscularly, by hand syringe, or by syringe dart, in the heavy muscles of the croup or shoulder as follows:

(A) Elk (*Cervus canadensis*): 0.25 to 0.5 mg/lb.

(B) Mule deer (*Odocoileus hemionus*), sika deer (*Cervus nippon*), and white-tailed deer (*Odocoileus virginianus*): 1 to 2 mg/lb.

(C) Fallow deer (*Dama dama*): 2 to 4 mg/lb.

(ii) *Indications for use.* (A) To produce sedation, as an analgesic, and as a preanesthetic to local anesthesia.

(B) To produce sedation, accompanied by a shorter period of analgesia. May be used to calm and facilitate handling of fractious animals for diagnostic procedures, for minor surgical procedures, for therapeutic medication for sedation and relief of pain following injury or surgery, and as a preanesthetic to local anesthetic. At the recommended dosages, can be used in conjunction with local anesthetics, such as procaine or lidocaine.

(iii) *Limitations.* Do not use in domestic food-producing animals. Do not use in Cervidae less than 15 days before or during the hunting season.

[68 FR 26206, May 15, 2003, as amended at 75 FR 10167, Mar. 5, 2010]

§ 522.2670 Yohimbine injectable.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains either 2 or 5 milligrams of yohimbine (as hydrochloride).

(b) *Sponsor.* See 061690 in § 510.600(c) of this chapter for use of 2 milligrams per milliliter solution in dogs.

(1) *Amount.* 0.05 milligram per pound (0.11 milligram per kilogram) of body weight.

(2) *Indications for use.* To reverse the effects of xylazine in dogs.